REMARKS

In an office action mailed June 16, 2006, claims 1-2 were rejected under 35 U.S.C. § 102(b), and claims 3-6 were allowed. In this document, new claims 7-8 are presented. Support for the new claims may be found, for example, in page 3, paragraph 0008 of the instant Specification.

The 35 U.S.C. § 102(b) Rejection

Claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as being anticipated by Rustum *et al. Journal of Chromatography* 421 (1987) 387-91. The Examiner contends that Rustum *et al.* teaches a method for quantifying 5-azacitidine in plasma comprising mixing plasma with acetonitrile and zinc sulfate; separating the mixture by centrifugation; storing the separated mixture at a temperature of less than or equal to about room temperature for at least about 3 hours, and measuring the amount of 5-azacitidine using HPLC.

Applicants traverse this rejection. Applicants respectfully disagree with the Examiner's contention that Rustum *et al.* discloses the step "storing the separated mixture at a temperature less than or equal to about room temperature for at least about 3 hours" (Office Action, page 2). The Examiner points to the subheadings "Procedure" and "Stability of 5 azacitidine in plasma" in the reference for support for this statement.

Applicants have carefully reviewed the reference and the sections pointed out by the Examiner. Applicants respectfully submit that the storage of the plasma referred to in the "Stability of 5-azacitidine in Plasma" section of Rustum *et al.* refers to storage of plasma (containing 5-azacitidine) only, not a mixture of plasma and acetonitrile/zinc. The "Stability of 5-azacitidine in Plasma" section of Rustum *et al.* describes an experiment where the authors determined the stability of 5-azacitidine upon storage in plasma, i.e., not storage in plasma/acetonitrile. See page 388 of Rustum *et al.*, which states "a plasma solution containing 20 μg/ml 5-azacitidine was transferred in approximately 2-ml volumes into borosilicate test tubes. Immediately, 1.0 ml was analyzed [by the acetonitrile method discussed in "Procedure"] and this was considered zero time . . . [p]eriodically another test tube's contents was analyzed . . . [t]he determinations were continued beyond 20% loss of 5-azacitidine. A similar procedure was used for samples stored at -10 and -60°C."

Applicants submit that the quotation from Rustum *et al.* shows that the plasma samples were stored for various times at various temperatures before analysis using the Rustum *et al.* acetonitrile method. The data obtained were used to generate Fig. 3 of Rustum *et al.*, showing the stability of 5-azacitidine in plasma.

Accordingly, Applicants submit that Rustum *et al.* fails to disclose a step of storing the centrifuged mixture of plasma and acetonitrile/zinc at a temperature less than or equal to about room temperature for at least about 3 hours, as recited in both claims 1 and 2. In contrast, Rustum *et al.* teaches syringe-filtering the clean supernatant and injecting into the chromatograph.

Accordingly, Applicants submit that Rustum *et al.* fails to disclose each and every element of claims 1 and 2 and accordingly, the rejection under 35 U.S.C. § 102(b) is not proper. Reconsideration is respectfully requested.

Applicants have also added new claims 7 and 8, directed to a mixture where the ratio of plasma to acetonitrile/zinc sulfate solution in step (a) is less than or about equal to 1:20 (v/v). Applicants note that Rustum *et al.* teaches addition of 200 ul of acetonitrile to 1 ml of a patient's plasma or control plasma, resulting in a far larger ratio of plasma to acetonitrile/zinc sulfate solution of 5:1 (v/v), in contrast to the 1:20 (v/v) ratio as claimed by Applicants. Allowance is respectfully requested.

Allowable Subject Matter

The Examiner notes that claims 3-6 are allowed. The Applicants thank the Examiner for noting the allowability of claims 3-6.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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Mary B. Smith

Mary B. Smith, #43,512
Swanson & Bratschun, L.L.C.
1745 Shea Center Drive, Suite 330
Highlands Ranch, Colorado 80129
Telephone: (303) 268-0066
Facsimile: (303) 268-0065

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